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10/630,441	07/29/2003	Alastair Hodges	LFSCAN.079C1C1	8256

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EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,441	HODGES ET AL.	
	Examiner	Art Unit	
	Kaj K. Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-27-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The new limitation requiring the coating to "not result in a loss of the desired sensing characteristics of the electrode" is vague and confusing because applicant hasn't specified what the desired sensing characteristic even is. What is the specified sensing characteristic (amperometric, potentiometric, capacitance, conductivity, etc) is this referring to? The claims and the specification do not elaborate. Furthermore, what is the "desired" referring to? Desired by the applicant or desired by the prior art? Because claims 1 and 18 don't even require the electrode to be a sensing electrode, it is unclear how the prior art can be evaluated against this new limitation. If for example the prior art utilized against the claims was not a sensing electrode, then presumably any coating containing a sulfur containing moiety would not result in a loss of a desired sensing characteristic because the reference doesn't have a desired sensing characteristic. Finally, this limitation was added to the claims in an attempt to read free of the prior art being utilized against the claims. Applicant urged that each of the coatings from these references failed to meet this new limitation. However, the prior art is utilizing the same sulfur containing moieties as claimed by the instant invention. See the previous office action and the rejections below. How can the prior art not meet this new limitation when they are relying on

the same sulfur containing moieties as that of the instant invention? Why do these coatings in the instant invention not cause a loss in desired sensing characteristic (whatever that unspecified sensing characteristic is), but yet are not met by the prior art disclosing those same materials?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by French et al (Langmuir, 3-19-1998, 14, 2129-2133).

6. French discloses a metal electrode coated with a sulfur containing moiety (n-alkane thiols) that improves the temporal stability of the electrode (see the "Introduction"). French further teaches the presence of an overcoating of a surfactant (octanol) on the thiol layer. See the abstract and the last four lines of the Introduction.

7. With respect to the new limitation requiring the coating not result in a loss of the desired sensitivity characteristic of the electrode, because French utilizes a thiol like the instant invention, it is interpreted as already meeting this set forth limitation (see 112 rejection above). Moreover, because French desired the function provided by the coating of the thiol (see first paragraph of the Introduction), it is clear that French does not consider the thiol to be an impediment to French's desired sensing characteristic.

8. With respect to the method of making the electrode, French first coats the electrode with the sulfur containing species and follows that with an overcoating of the surfactant. See "Monolayer Preparation" and "Electrochemical Experiments" on p. 2130.

9. With respect to the method of using the electrode (those limitations not covered above), French is monitoring the response of ferricyanide, which reads on the broadly defined obtaining a measurement indicative of an analyte.

10. Claims 1, 2, 6, 7, 10, 11, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Schweiss et al (Material Science Forum (1998), pp. 287-288). The examiner previously relied on the CAPLUS abstract for the Schweiss. The examiner is now relying on the published document, which has now been made available to the examiner.

11. Schweiss discloses an electrode coated with a sulfur containing thiol molecule and further teaches that this electrode has an overlayer of surfactant. See fig. 1.

12. With respect to the new limitation requiring the coating not result in a loss of the desired sensitivity characteristic of the electrode, because Schweiss utilizes a thiol like the instant invention, it is interpreted as already meeting this set forth limitation. Moreover, because Schweiss presumably desired the function provided by the coating of the thiol, it is clear that Schweiss does not consider the thiol to be an impediment to Schweiss's desired sensing characteristic. In fact, Schweiss is monitoring the capacitance of the thiol monolayer as a function of surfactant absorption and the thiol is not interfering with the capacitance measurement.

13. With respect to a hydrophilic group, the thiols utilized by Schweiss (16-Mercaptohexadecanoic acid and 20-Mercaptoeicosane-1-thiol) are terminated with carboxyl and

amine groups respectively with alkyl spacers. See the attached Registry report for these two molecules.

14. With to the method of making the electrodes (those limitations not covered above), Schweiss first applies the monolayer coating followed by the surfactant (see the abstract).

15. With respect to the broadly claimed method of using, Schweiss is utilizing the electrode for the monitoring of surfactant analytes.

16. Claims 1, 2, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Dong et al (Bioelectrochemistry and Bioenergetics, 42 (1997), pp. 7-13).

17. Dong discloses an electrode comprising a coating of alkanethiol (i.e. a sulfur containing moiety) with an overcoating of a lipid molecule. See fig. 9 and the section 3.3. The examiner is of the opinion that a lipid molecule would read on surfactant because it would reduce the surface tension between the hydrophobic monolayer and the water solution by virtue of its hydrophobic tail and hydrophilic head. The examiner notes that surfactants, including applicant's own Triton-X, typically consist of hydrophilic heads with hydrophobic tails.

18. With respect to the new limitation requiring the coating not result in a loss of the desired sensitivity characteristic of the electrode, because Dong utilizes a thiol like the instant invention, it is interpreted as already meeting this set forth limitation. Moreover, Dong is utilizing its combination of thiol and lipid layer to support molecules having a monovalent selectivity (see section 3.3, particularly the paragraph preceding fig. 9). Hence, the desired sensing characteristics of Dong is for monovalent ions and it is presumed that this would meet the vaguely defined absence of loss of sensing characteristics.

19. With respect to claim 18 (those limitations not covered above), Dong teaches painting the lipids onto the monolayer containing electrode to result in the overlayer. See section 3.3.

20. With respect to claim 19 (those limitations not covered above), Dong teaches measuring the presence of sodium, potassium and lithium ions.

Claim Rejections - 35 USC § 103

21. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

22. Claims 1-7, 10-13, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al (J. Electroanal. Chem., 178 (1984), pp. 69-86) in view of French.

23. With respect to claim 1, Allen discloses a coated metal electrode comprising numerous different sulfur-containing moieties for said coating. See p. 72 for a discussion of the metal electrode and table 1 for a listing of the moieties being relied on. Allen does not explicitly disclose overcoating this coating with a surfactant. French the desirability of adding a surfactant to the monolayer so as to improve the barrier properties of the monolayer itself. to prevent species from leaking through defects in the monolayer thereby forcing the electrochemistry to proceed through the sulfur-containing moiety (i.e. direct electron transfer). See the Introduction of French. It is noted that Allen is utilizing the sulfur-containing moiety as a direct electron transfer means (see the Introduction) and would benefit from the removal of defect related electron transfer. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of French for the electrode of Allen so as to prevent defect related electron transfer.

24. With respect to the new limitation requiring the coating not result in a loss of the desired sensitivity characteristic of the electrode, because Allen is utilizing many of the same molecules as taught by the instant invention (see below), it is interpreted as already meeting this set forth limitation. Moreover, Allen is utilizing these molecules to improve the electron transfer to the cytochrome-c. Hence, Allen clearly does not consider these molecules to be an impediment to the desired sensing characteristics.

25. With respect to claims 2-4, see structures 2, 19 and 46 from fig. 3.

26. With respect to claim 5, see elements 28-30 of Table 1.

27. With respect to claims 6 and 7, see structures 4, 10a, 14a-16a from fig. 3.

28. With respect to claims 10 and 11, see structure 4 from fig. 3.

29. With respect to claim 12, this only further limits claim 11 when alkyl groups are chosen from claim 11. Because Allen teaches the use of aromatic groups (see above), Allen reads on claim 12 when aromatic groups are chosen from claim 11.

30. With respect to claim 13, see elements 7 and 28 from table 1.

31. With respect to claim 18 (those limitations not covered above), French teaches exposing the electrode to the surfactant after the application of the monolayer of thiol (see 102 rejection with French above).

32. With respect to claim 19 (those limitations not covered above), Allen utilizes the electrode as a measurement means for determining the presence of cytochrome c in the solution (see abstract, pp. 72-75 and fig. 1). This would read on the claimed "obtain a measurement indicative of a presence of an analyte in the sample".

33. Claims 1, 2 and 6-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlereth et al (Electroanalysis 1995, 7 (1), pp. 46-54) in view of French.

34. With respect to claim 1, Schlerich discloses a coated metal electrode were the metal electrode comprising a coating of a sulfur containing moiety comprising cysteine. See Abstract and Scheme 1. Schlerich does not explicitly disclose the use of an overcoating of surfactant. French teaches the addition of a surfactant to a monolayer coated surface so as to form a overcoating that seals in the defects of the monolayer thereby preventing the contact with interfering electroactive species. See rejection above and note that Schlerich repeatedly teaches that monolayer surface coverage was low (i.e. high concentration of defects) (see section 3.1). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of French for the electrode of Schlerich so as to prevent the interference from other electroactive species.

35. With respect to the new limitation requiring the coating not result in a loss of the desired sensitivity characteristic of the electrode, because Schlerich is utilizing a molecule explicitly disclosed by the instant invention, Schlerich is interpreted as already meeting this set forth limitation. Moreover, Schlerich is utilizing the molecules in question to favorably attach to the electrodes molecules that are to be sensed. Hence, Schlerich would presumably meet the vaguely defined absence of loss of desired sensing characteristics.

36. With respect to claim 2, see scheme 1 of Schlereth.

37. With respect to claims 6-9 and 13, see the cysteine of scheme 1.

38. With respect to claims 10 and 11, scheme 1 also shows examples of alkyl and aromatic spacers.

39. With respect to claim 12, this only further limits claim 11 when alkyl groups are chosen from claim 11. Because Schlereth teaches the use of aromatic groups (see above), Allen reads on claim 12 when aromatic groups are chosen from claim 11.

40. With respect to claims 14-17, cysteine is inherently a stereospecific molecule. Although Schlereth does not specify which form of cysteine is present, Schlereth discusses no criticality as to the choice of isomer is present and one possessing ordinary skill in the art would have been motivated to utilize either the D or L isomer (or both) because they would all provide the desired monolayer for the electrode.

41. With respect to claim 18 (those limitations not covered above), French teaches exposing the electrode to surfactant after the application of the monolayer of thiol (see 102 rejection with French above).

42. With respect to claim 19 (those limitations not covered above), Schlereth utilizes the electrode to obtain a measurement of phenothiazine or NADH. See section 1 or 3.1. This would read on the claimed "obtain a measurement indicative of a presence of an analyte in the sample".

Response to Arguments

43. Applicant's arguments filed 8-8-2006 have been fully considered but they are not persuasive. Applicant urges that French does not teach that the coating does not result in a loss of the desired sensing characteristics of the electrode because the 1-octanol (i.e. the surfactant) of French is being utilized to prevent direct electron flow of the electrode. This argument is unpersuasive for a number of reasons. First, applicant's arguments largely concern the function of the overcoating (i.e. surfactant) of French. However, the claim amendments are merely

calling for the coating to not result in a loss of desired sensing characteristics. Whether or not the surfactant overcoating would result in a loss of desired sensing characteristics is moot because applicant isn't claiming that the overcoating must not result in a loss of desired sensing characteristics for the electrode. Second, even if the examiner ignored the whole distinction between the coating and overcoating, it is unclear why the applicant believes that these coatings of French read free of the broadest reasonable interpretation of vaguely defined, desired sensing characteristics. In particular, applicant appears to be of the opinion that because French is attempting to prevent direct electron transfer, then that would constitute a loss of the desired sensing characteristics of the electrode. However, it isn't clear that French wants direct electron transfer. Hence, the absence of direct electron transfer wouldn't constitute a loss in French's desired sensing characteristics. There is nothing inherent in the term "desired sensing characteristics" that the desired sensing characteristic must involve direct electron transfer. Third, as discussed above in the rejection, it is unclear what the distinction is between the coatings of the instant invention and the monolayer coatings known in the art (i.e. French). Applicant particularly claims the use of thiols, which French possesses. Why is French's use of a thiol coating (i.e. monolayer) any different from the thiol coatings of the instant invention? It appears as if the applicant is attempting to claim a new function (i.e. preventing unwanted hydrocarbons contaminants) by doing what is already old in the art (i.e. coating the electrode with a thiol monolayer). A new reason for doing what is already old in the art does not impart patentability over the prior art.

44. With respect to French and Schweiss, applicant urges that these references do not teach the use of SAMs to prevent unwanted hydrocarbon contaminants from altering the

electrochemical behavior of the electrode. However, as discussed above, a new reason for doing what is already old in the art does not impart patentability over the prior art. Applicant also urges that Schweiss also does not retain the sensing characteristics of the electrode. However, Schweiss's desired sensing characteristic is capacitance and it doesn't appear that the monolayer has prevented such a measurement.

45. With respect to the rejection of Dong, applicant urges that the lipids of Dong would not read on the defined surfactant. In particular, applicant urges that surfactants are polar compounds that are generally water loving. Applicant's definition of surfactant is too narrow. A surfactant is simply a material that can reduce interfacial tension between two liquids or between a liquid and a solid. There is no inherent requirement that surfactants are polar (although they typically are) nor is there a requirement that they be water loving. For example, surfactants having a low hydrophilic-lipophilic-balance (HLB) are not water loving and are oftentimes only sparingly soluble in water. With respect to the examiner broadest reasonable interpretation of a surfactant, the lipid of Dong meets the definition, because it has a polar hydrophilic end (i.e. the ball of the lipid in fig. 9) out in the water solution with its hydrocarbon (lipophilic) tail mated against the hydrocarbon tail of the thiol monolayer. This combination of hydrophobic end in the water solution and the lipophilic tail against the lipophilic tail of the thiol meets the requirement that the lipid reduce interfacial tension. Compare the lipid in fig. 9 of Dong with the surfactant in fig. 1 from Schweiss. Both the lipid of Dong and the surfactant of Schweiss constitute the same basis structure.

46. Applicant also urges that the lipids (i.e. overcoat) of Dong would impede electrolytes from the solution thus altering the electrochemical behavior of the electrode. However, as

discussed above with French, applicant is not claiming that the overcoat not result in a loss of desired sensing characteristic but rather the coating itself. Moreover, Dong is utilizing its combination of coating and overcoating to hold molecules having monovalent selectivity so that those monovalent ions can be sensed. Hence, the desired sensing characteristic of Dong is monovalent ions and there is no indication that the coating prevents the sensing of those ions.

47. With respect to the rejections relying on Allen, applicant urges that the teaching of French would disrupt the interactions between the cytochrome-c in solution and the surface modifying groups (i.e. the coating). However, the cytochrome-c is not in solution *per se* but rather is hydrogen bonded to the sulfur containing coating. See the abstract and the first figure of p. 80. Allen is relying on the direct electron transfer between the cytochrome-c and the surface modifier. Hence, the surface modifying groups and cytochrome-c form a continuous structure that would permit direct electron transfer. What French teaches is that a surfactant added to a monolayer will fill in defects at the electrode surface and also forms a thin film over the monolayer itself. See scheme 1 and p. 2129. Hence, if Allen added a surfactant *after* the surface modifier and cytochrome-c were already present and tethered together, the surfactant in question would fill in the defects of the electrode surface not covered by the coating and would overcoat the portions of the surface modifier that are not tethered to the cytochrome-c thereby ensuring that the measured electron transfer occurs only at locations where cytochrome-c is tethered to the surface modifier.

48. With respect to the rejections relying on Schlereth, applicant urges that Schlereth does not teach improving the temporal stability while retaining the desired sensing characteristics of the electrodes. It is unclear how applicant came to this conclusion based on the fact that

Schlereth utilizes a coating of cysteine, which the applicant has explicitly claimed as providing these favorable properties (see claim 13).

Conclusion

49. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
October 12, 2006

KAJ K. OLSEN
PRIMARY EXAMINER